

	<b><u>MOREHOUSE SCHOOL OF MEDICINE POLICIES AND PROCEDURES</u></b>	POLICY NUMBER	COMPLIANCE
		EFFECTIVE DATE	10/10/2019
	<b><u>SUBJECT</u></b>  <b>CONFLICTS OF COMMITMENT AND CONFLICTS OF INTEREST POLICY AND DISCLOSURE REQUIREMENTS</b>	Pages	14
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**OVERVIEW:**

Consistent with Morehouse School of Medicine's ("MSM") research, teaching, patient care, and public service mission, MSM encourages MSM personnel -- trustees, administrators, faculty, staff, and trainees -- to engage in appropriate professional and business interactions with public and private entities. Because some activities can create direct, indirect or the appearance of conflicts that affect MSM's interests, compromise objectivity, or influence performance of MSM's responsibilities, MSM requires such activities to be reported, reviewed, and managed in accordance with this Policy. Some professional and business relationships require greater vigilance than others. For example, when a relationship with a business entity could influence decisions made in the conduct of research involving human subjects or in the provision of clinical health care, ensuring the safety of research participants and patients is paramount. All members of the MSM community must report a potential conflict of interest, especially when he or she or a member of his or her family possesses a personal or financial interest or is engaged in an Outside Professional activity related to his or her MSM responsibilities.

**PURPOSE:**

Members of the MSM community are expected to conduct the affairs of MSM consistent with high ethical and legal standards and in a manner that will further the interests of the MSM community. As part of this responsibility, MSM personnel are expected to apply their time and effort appropriately, to use MSM resources toward MSM ends, and to avoid any interaction that creates or appears to create a Conflict of Interest or Conflict of Commitment, as defined below. Accordingly, this Policy establishes standards and requirements to protect the financial well-being, reputation, and legal obligations of MSM. Furthermore, this Policy establishes a method to protect the MSM community from questionable circumstances that might arise and to resolve any apparent or real conflicts. Consequently, an integral part of this policy is the required disclosure of actual or potential conflicts of interest and commitment consistent with this policy and to cooperate in the remedy of any actual or potential conflicts.

## **DEFINITIONS:**

**Business** means any company or corporation, partnership, sole proprietorship, firm, franchise, association, organization holding company, joint stock company, receivership, trust (business, real estate, estate planning or otherwise), enterprise or any other legal entity.

**Conflict of Commitment** arises when an individual's obligation to MSM is compromised by commitments of time to other entities or activities. Commitments to "other" entities or activities may include, but are not limited to, consulting, participation in civic or charitable organizations, obligations to or with professional societies, attendance at conferences and meetings, working as a technical or professional advisor or practitioner, or holding a part-time job with another employer, whether working in one's Morehouse School of Medicine occupation or another and other outside obligations (compensated or uncompensated).

**Conflict of Interest** means a situation in which an individual's financial professional or other personal considerations may directly or indirectly affect, or have the appearance of affecting, the individual's professional judgment in exercising any MSM duty or responsibility, including any research activities or services conducted at or on behalf of the institution.

**MSM Community Members** includes all MSM personnel, including trustees, administrators, faculty and staff. Any member of another institution who is engaged in research at facilities owned, leased or operated by MSM and who contributes substantively to the design, conduct or reporting of research, and which research is supported by MSM or funds designed for MSM's use. Also, see definitions for Faculty and Staff below.

**Faculty**, for purposes of this Policy, means any person possessing either a full- or part-time academic appointment at MSM, including faculty-level research appointees, faculty librarians, health system clinicians, and contributed service faculty.

**Family Member** includes a spouse, domestic partner, children (including stepchildren), parents, siblings, aunts, uncles, nephews, nieces, grandparents, grandchildren (whether related by blood, marriage, adoption, including a person having a step-relationship with any of the foregoing person(s)), father-in-law and mother-in-law, brothers-or sisters-in-law, and any person who resides in the same household as the MSM Community Member.

**Investigator** is any individual acting as a project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, and the individual's Family Member, as defined above.

**IRB ("Institutional Review Board")** means any board, committee, or other group formally designated by MSM to review human subjects research, and which was established and which functions and operates in conformity with Part 46 of Title 45 and Part 56 of Title 21 of the Code of Federal Regulations. IRB Members are those persons who comprise the IRB.

**Leadership Role** means employment, consulting in any administrative or executive capacity, or serving as (i) a member of a board of trustees or board of directors, (ii) an officer, or (iii) a member of an advisory committee, advisory board or subcommittee of a board of trustees or a board of directors, whether remunerated or non-remunerated, in a research **Sponsor** or research-related organization.

**Institution Project** means any research, testing, evaluation, training, and/or instructional project conducted under the auspices of the Institution.

**Institutional Responsibilities** means an individual's responsibilities on behalf of MSM, such as research, teaching and institutional committee memberships.

**Outside Professional Activities** is any paid or volunteer activity undertaken by a member of the MSM Community outside the scope of his or her regular Morehouse School of Medicine duties. Outside Professional Activities may include, but are not limited to, consulting, participation in civic or charitable organizations, obligations to or with professional societies, attendance at conferences and meetings, working as a technical or professional advisor or practitioner, or holding a part-time job with another employer, whether working in one's Morehouse School of Medicine occupation or another and other outside obligations (compensated or uncompensated).

**Staff** means any regular, non-exempt and exempt staff in research, academic or administrative positions, including residents, postdoctoral fellows, research associates, counselors, non-faculty physicians and non-faculty veterinarians.

## **POLICY**

It is the Policy of MSM that in pursuing its mission the school must conduct its business free of improper influence resulting from external relationships. Given the breadth of MSM's activities, the variety of its relationships, and the need for the school to act as a wise steward of all its resources, the creation of MSM relationships that are a direct, indirect or have the appearance or effect of a conflict of interest, is unavoidable. Members of the MSM Community are required to ensure that no conflict of interest or conflict of commitment interferes with their ability to perform their responsibilities for the benefit of MSM. These relationships must be identified promptly, reported and resolved appropriately. A relationship that may initially appear to result in a conflict of interest may not in fact do so. Determining whether such a conflict exists requires careful consideration of all available relevant information, and therefore all potential conflicts must be reported and resolved in accordance with this Policy.

## **GUIDELINES FOR SPECIFIC AREAS OF POTENTIAL CONFLICT**

MSM strives to ensure that all of its activities are conducted in accordance with high ethical standards and in compliance with federal and state laws and regulations. Some activities by their nature require particular scrutiny for potential conflicts of interest. The following are guidelines that MSM Community Members should follow. Disclosure and approval are required before engaging in activities that are inconsistent with these guidelines.

## **I. Conflicts of Commitment**

The term "Conflict of Commitment" relates to an individual's distribution of effort between MSM duties and Outside Professional Activities. The responsibility for addressing conflicts of commitment rests, in the first instance, with the individual. All MSM Community members are expected to devote their primary professional loyalty, time and energy to their MSM responsibilities; accordingly, Outside Professional Activities must be arranged so as not to interfere with the primacy of MSM responsibilities.

Each member of the faculty shall advise their department chair and dean in advance of any activities in which he/she engages which will or may result in rendering less than full-time service to MSM. External opportunities will not be allowed to interfere with the responsibilities of the faculty member to the department or major academic unit. The chair of each major academic unit shall approve such outside employment and commitments by the faculty member. MSM policy does not provide that a faculty member is entitled to engage in external professional activities for pay for any specific or set percentage of time. Rather, an individual's supervisor always has the discretion to determine whether a proposed external activity is appropriate in scope and duration or constitutes excessive time away from MSM duties. Furthermore, MSM's name may not be used for personal promotional purposes or for personal gain.

Non-faculty members of the MSM Community who hold full-time appointments are expected to devote their full-time professional loyalty, time and energy to their MSM position. Outside employment is permitted as long as the nature of the employment is not in direct competition or conflict with MSM's mission or the mission of the individual's department. Furthermore, the time and effort required by the outside employment must not in any way restrict or prevent the individual from performing his/her MSM duties and responsibilities. Some departments may require the individual to obtain pre-approval by the Director or Unit Head before beginning outside employment. In no case are individuals with full-time or part-time staff/administrative positions permitted to perform duties for another employer (including self-employment) during his/her normal working hours at MSM.

## **II. Conflicts of Interest**

Considerations of personal gain must not influence the decisions or actions of individuals in discharging their MSM responsibilities. Such incentives might create a perception of impropriety and, therefore, require that such conflicts be identified, and then managed, reduced, or eliminated.

The following activities are examples of situations that may raise questions regarding an apparent or real Conflict of Interest:

- 1) Undue personal gain from MSM funds or resources;
- 2) Excessive or unauthorized use of MSM time or resources for professional, charitable, or community activities;

- 3) Exploitation of students for private gain;
- 4) Compromise of MSM priorities due to personal financial considerations;
- 5) Unfair access by an outside party to MSM programs, services, information, or technology;
- 6) Selection of an entity as an MSM vendor by an individual who has a personal or economic interest in that entity; this includes engaging a family member as an independent contractor, subcontractor, or consultant; or
- 7) Acceptance of a gift or favor from an entity (or representative of an entity) conducting (or seeking to conduct) business with MSM, when a Faculty or Staff member is in a position to influence or inform decision-making relative to engaging the Entity on behalf of MSM.

MSM will exercise oversight and care in eliminating or managing Conflicts of Interest that do or may arise because of an individual's personal interest in activities related to their Institutional Responsibilities. MSM will not accept or enter into agreements, contracts, gifts, or purchases that give rise to a Conflict of Interest unless the conflict can be eliminated or appropriately managed through administrative oversight to protect the interests of the individual and MSM.

### **III. Appropriate Use of MSM Resources**

MSM resources are to be used only in the interest of MSM. Members of the MSM Community may not use MSM resources, including facilities, personnel, equipment, or confidential information, as part of their external activities or for any other non-MSM purposes unless MSM has contracted to provide such resources under an appropriately approved MSM agreement.

Confidential or privileged information acquired by MSM may not be used by an individual for personal gain, nor may any individual permit unauthorized access to such confidential or privileged information. Members of the **MSM Community should be wary of consulting arrangements through which they may risk sharing confidential proprietary information acquired through sponsored MSM projects.**

Members of the MSM community may not use for non-MSM purposes any MSM-funded or supported resources, including but not limited to MSM facilities, work product, results, materials, property, records, or information developed with MSM funding or other MSM support except as otherwise allowed under MSM policy. This prohibition includes the use of MSM's name in a manner that may imply that MSM is associated in some way with the individual's external activity or interest. One context in which this might occur is an Outside Professional Activity for pay. Mere identification of MSM as one's employer and of one's position at MSM is permitted, provided that such identification is not used in a manner that implies sponsorship or endorsement by MSM.

Inappropriate use of MSM resources includes, but is not limited to, the following examples:

- 1) A Faculty member assigning students, staff, or postdoctoral scholars MSM tasks to advance the Faculty member's own monetary interest rather than to advance the scholarly field or educational needs;

- 2) Granting external entities access to MSM programs, resources, services, information, or technology for purposes outside of MSM's mission;
- 3) Offering inappropriate favors to outside entities in an attempt to unduly influence them in their dealings with MSM; and
- 4) Using for personal gain, or granting others unauthorized access to, confidential information acquired through conduct of MSM business or research activities.

#### **IV. Guidelines for Specific Areas of Conflicts of Interest or Conflict of Commitment**

##### **A. Outside Professional Activities**

###### **1. Staff**

A Staff member wishing to engage in an Outside Professional Activity that may present a Conflict of Commitment or Conflict of Interest must provide a written request to the Staff member's immediate supervisor or department/unit head prior to engaging in the activity. Upon consideration of the request, if the supervisor or department/unit head determines that an actual or perceived Conflict of Commitment or Conflict of Interest exists given the relation of or impact on the external or personal activity to the Staff member's Institutional Responsibilities, management strategies may be established. The Office of Compliance and Corporate Integrity can serve as a resource to help supervisors and department/unit heads navigate and handle such requests, and can advise as to appropriate management strategies, if/as applicable. Permission is left to the discretion of the supervisor or department/unit head and may be given if the proposed activity does not compete with MSM activities and does not interfere with or detract from the performance of the Staff Member's Institutional Responsibilities. MSM time and resources may not be used in any way for external activities. If the Outside Professional Activity meets the disclosure criteria outlined in this Policy and in the annual disclosure questionnaire, the Staff member must disclose it in MSM's disclosure system, COI-Smart, during the subsequent annual disclosure process or sooner if/as advised or required.

Outside Professional Activities that use Institution resources or an individual's time on the job, thereby competing with the Institution or conflicting with the performance of the job, present a Conflict of Commitment or Conflict of Interest and are not permitted.

###### **2. Faculty**

Appointment as a Faculty member of MSM confers the obligation to pursue teaching, research, and/or Institutional service. Fulfillment of these obligations requires a primary professional commitment of expertise, time, and energy. Faculty engagement in Outside Professional Activities is a privilege and not a right and must not detract from a Faculty member's obligation to Institutional duties.

A full-time appointment conveys an obligation for a Faculty member to have a significant physical presence on campus, to be accessible to students and Staff, to carry the faculty member's share of committee responsibilities, to meet any assigned obligations, and to be available to interact with MSM colleagues, unless the relevant department chair and/or school dean has granted specific prior approval for extended or frequent absences from

campus. Activities such as pro bono work, government service in the public interest, and any outside employment unrelated to the Faculty member's Institutional Responsibilities must be managed so they do not take precedence over a Faculty member's primary professional commitment to MSM.

Significant management roles (those that involve substantial supervision of the work of others and/or day-to-day responsibility for operating decisions) in private business typically are demanding both in terms of time and energy. Because full-time Faculty are expected to devote their primary professional energies and interests to their Institutional Responsibilities, they may not accept significant managerial responsibilities as part of their Outside Professional Activities. It will be necessary for a Faculty member to obtain the permission of the member's chair and/or school dean and may require an unpaid leave of absence from his or her Institutional Responsibilities in order to take on a significant management role in an outside entity.

Certain Outside Professional Activities, such as submitting or directing a program of research or scholarship at another institution that could be conducted appropriately at MSM, can generate conflicts regardless of the time involved. Absent express approval by the relevant chair and/or school dean, MSM Faculty are prohibited from serving as principal investigators on sponsored projects submitted and managed through other academic, federal, or commercial institutions. This stipulation does not apply to subcontracts awarded to the Institution; it is not intended to limit Faculty members' participation in multi-site training or research programs, nor is it intended to apply to circumstances in which the Faculty member's research requires access to facilities not available at MSM.

#### **B. Use of Students in Outside Professional Activities**

Student involvement in Faculty enterprises may provide the potential for substantial benefits to the education and career development of the student. Such involvement needs to be guided to avoid Conflicts of Interest or interference with the student's primary educational and research duties. Before engaging in these activities, whether paid or unpaid, Students and Faculty must request approval in writing from the school's dean or the dean's designee.

#### **C. Use of Staff in Outside Professional Activities**

Members of the MSM Community may not require those they supervise to perform services outside those related to their Institutional Responsibilities. It may be appropriate for Staff to assist Faculty members in their Outside Professional Activities, depending upon the nature and extent of the Staff involvement and whether it is on an incidental or infrequent basis. However, because such involvement is a potential source of conflict, Members of the MSM Community must receive approval from the relevant department chair, center director, or dean, before involving a member of the MSM Community in his or her Outside Professional Activities.

#### **D. Financial Interests**

Financial Interests can create Conflicts of Interest when they provide, or appear to provide, an incentive to a member of the MSM Community to affect an MSM institutional decision or other MSM institutional activity (for example, because of the possibility for personal gain) and when the individual has the opportunity to affect an MSM institutional decision or other MSM institutional activity (for example, because the individual is the principal investigator for a

research project or has institutional purchasing authority relative to use of an external vendor). If there is both sufficient incentive from the Financial Interest and the opportunity to affect the institutional activity or decision, a Conflict of Interest exists.

For purposes of this Policy, "Financial Interest" is one or more of the interests defined below held by a member of the MSM Community if the interest reasonably appears to relate to the individual's Institutional Responsibilities:

1. With regard to any publicly traded entity, a Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated for the individual and his or her family members, exceeds \$5,000 or is more than five percent (5.0%) of a company's equity for any single business. For purposes of the definition of Financial Interest, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
2. With regard to any non-publicly traded entity (e.g., a start-up company), a Financial Interest exists if (a) the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated for the individual or his or her Family Members, exceeds \$5,000 or (b) the individual or the individual's Family Member holds any equity interest in the entity, even if the value of such interest is zero or is unknown; or
3. With regard to intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
4. With regard to travel expenditures, reimbursed travel expenditures exceeding \$5,000 from a single entity.

All individuals must report any potential conflict of interest arising from their personal financial interests to their immediate supervisors at the earliest opportunity where such a potential institutional conflict meets the test set forth above, such employees should, where feasible, recuse themselves from involvement in MSM business involving entities with whom they have financial relationships. An individual's supervisor must concur in the individual's decision to recuse him or herself. In some cases, it will be impossible for such individuals to recuse themselves and conduct their MSM duties effectively. In such instances they must divest themselves of the personal financial interest creating the institutional conflict. Both the disclosure to the individual's supervisor and the decision to recuse or divest should be documented in the employee's personnel file.

## **V. Acceptance by Individuals of Gifts, Favors from External Entities**

Generally, MSM employees may neither accept nor offer, either directly or indirectly, any personal gift or favor or loan to or from an organization, entity or person that is conducting or

seeking to conduct business with MSM, unless the gift is nominal. A “nominal” gift occurs where the fair market value of all payments, gifts or favors from the same or related source within a single calendar year is less than one-hundred dollars (\$100.00). Although customary honoraria and reimbursement for actual costs generally are not considered to be gifts, if reimbursements or honoraria are significantly in excess of fair market value or customary amounts (e.g. expensive resort sojourns, coverage of family member expenses, etc.), they are de facto gifts. MSM employees also may not accept any financial or other favors in exchange for privileged access by current or potential MSM vendors to MSM facilities or employees. A MSM employee may not receive compensation from an external source for performance of MSM work except through a MSM contract or grant.

Gifts of any value from representatives of pharmaceutical, biotechnology, medical device, and the hospital equipment supply industry (“Industry”) are prohibited. The Physician Payments Sunshine Act is designed to increase transparency around the financial relationships between physicians, teaching hospitals and manufacturers of drugs, medical devices and biologics. The Centers for Medicare & Medicaid Services (CMS) fulfills the law’s mandate via the Open Payments Program. MSM’s Office of Compliance and Corporate Integrity use this program to assist in the verification of reported conflicts. MSM’s Community Members’ Interactions with Industry are governed by the institution’s Policy and Guidelines for Interactions with Pharmaceutical, Biotechnology, Medical Device and Hospital and Research Equipment Supply Industry.

#### **VI. Gifts to MSM or an Affiliated Foundation for the Benefit of an Individual Employee or Student**

For purposes of this Policy, gifts and donations that have been made to MSM or to a MSM affiliated foundation for the benefit of the professional activities of a specific faculty or staff member or student or trainee are considered to be a personal financial interest of the intended beneficiary, even though such gifts or donations are not the legal property of the beneficiary.

Such gifts and donations, where they coincide with MSM activities undertaken by the beneficiary that relate to the entity making the gift or donation, may create a conflict of interest, and they shall be reported by that individual as required under this Policy for any other personal financial interest.

#### **VIII. Purchasing, Contracting, and Other Business Transactions on behalf of MSM**

A member of the MSM Community generally may not participate in awarding, negotiating, reviewing or approving a financial transaction (including but not limited to purchases, contracts, and subcontracts) involving MSM and an entity in which the individual has a financial interest, including but not limited the financial interest of a Family Member.

Individuals involved in decisions relative to selecting vendors and/or that are involved in making certain purchasing decisions are subject to additional disclosure requirements in accordance with MSM’s Purchasing Policy and Procedures.

Where MSM proposes to conduct business with an entity with which it has a financial relationship, the entire transaction between the parties must be included in a written contract. Inclusion of all points of agreement between MSM and such entities is critical to avoiding the

appearance, whether or not warranted, that MSM may have conferred improper benefits on an entity with which it has a financial relationship. Where a contract is appropriate to the relationship, such contracts should be awarded through the use of transparent procedures for solicitation and award of contracts, such as those used by the MSM Procurement Process.

## **IX. Intellectual Property Transactions**

MSM's mission includes fostering the invention and development of new patentable and non-patentable technologies. MSM attempts to license many of these innovations to commercial entities so that MSM research results may reach the market for the public good. MSM must be protected from both real and perceived inappropriate "pipelining" of MSM innovations to entities in which MSM inventors have personal financial interests, and MSM facilities and resources must not be used to the advantage of the licensee entity absent specific authorization consistent with MSM policy and procedures.

## **X. Start-up Companies**

Direct investments by MSM in school-related start-up companies warrant particular sensitivity to ensure that no violations of this Policy occur as a result of such investments. Additionally, individual relationships with "start-up" ventures (relatively newly formed, privately held, for-profit companies that often may be based on intellectual property developed by the individual at MSM or elsewhere) present opportunities for development and commercialization of inventions but may also create conflicts of interest and commitment. While close involvement of the individual is often critical to the further development of the technology, multiple relationships of the individual with the start-up venture magnify the concern regarding the individual's commitment to their University responsibilities.

Use of MSM space by a startup is generally not permitted, except a startup may use MSM equipment or laboratories subject to a written agreement with MSM, and with strict limitation as to time and extent and only after review and approval by the Office of General Counsel.

## **XI. Exercise of MSM Administrative Responsibilities**

Individuals in administrative positions have substantial influence by virtue of their role in professional appointments, promotions, tenure decisions, allocations of space, determinations of salary, execution of business contracts, etc., and must take particular care to avoid relationships that have the potential to advantage the individual but adversely affect MSM's interests or inject inappropriate considerations into administrative decisions. They must be vigilant in ensuring that their exercise of administrative decisions are not, and do not appear to be, colored by their personal financial interests.

## **XII. Research Activities**

MSM's Research Conflicts of Interests Policy establishes standards and procedures to ensure that the design, conduct and reporting of sponsored research and educational activities will not be compromised by any conflicting financial interest and has implemented a system for the

disclosure, evaluation, and management, reduction and/or elimination of potential conflicts of interest. The Research Conflicts of Interests Policy complies with the federal regulations regarding objectivity in research (42 C.F.R. Part 50 Subpart F and 45 C.F.R. Part 94). The Research Conflicts of Interest Policy applies to all federally funded Public Health Service (“PHS”) grants, cooperative agreements, research contracts (but not Phase 1 SBIR or STTR program grants), and subawards where the originating sponsor is the PHS.

There are also important conflict of interest responsibilities for individuals participating on panels providing administrative review and evaluation on behalf of MSM, such as Institutional Review Boards (IRB) and Conflict of Interest review committees, and includes all individuals of any institutional office or body at MSM who performs research oversight functions in which they exercise professional or administrative-level discretion.

Federal law requires that IRB members not have any conflicting interests in the research that they review. MSM is concerned, as are various professional organizations, with the possible influence of such financial interests on research integrity and on the safety and welfare of human subjects involved in research protocols regardless of the source of research funding. MSM is also concerned with any Leadership Roles that may be held by IRB members in any entities that sponsor research, or that perform support, marketing, recruitment, data analysis or FDA liaison activities for research.

Consistent with federal law and the ethical principles of human subject research, MSM seeks to ensure that its research oversight officials can carry out their responsibilities to protect the rights and welfare of human subjects participating in research projects at MSM. Since MSM recognizes that real, potential and apparent conflicts of interest may occur during research, this policy is intended to assist IRB members as well as other research oversight officials in determining when they have Conflicts of Interest in research and to guide them in disclosing all potential conflicts and then, as appropriate, cooperate in the management or elimination of the conflicts.

Because IRB members and other research oversight officials have primary responsibility for protecting the safety and welfare of human subjects participating in research at MSM, it is the policy of MSM that IRB members and research oversight officials may not review any research protocol in which a decision to approve or disapprove the protocol could affect the IRB member’s or research oversight official’s or their family member’s financial interests. In particular, IRB members and research oversight officials may not have financial interests in any research sponsor or health-care related organization, nor any Leadership Roles in any research sponsor or research-related organization that could affect their review of research.

Each member of the MSM community who is engaged in research activities and who has an interest in a business or ownership (full or partial) of intellectual property who are proposed to do business or does business with the College must abstain from any oversight over associated grants, clinical trials or research. Oversight activities prohibited include providing administrative reviews, approval or supervision of research activities.

Federal agencies have specific regulations governing research. Each member, as principal investigators (P.I.), who conducts research must follow the provisions, protocols, procedures, requirements, and mandates of the agency under which funding occurs as stipulated and overseen by Institutional Review Boards (IRBs). Zero tolerance in adherence to all areas of

compliance is expected and mandated. MSM researchers are encouraged to check with the Office of Grants and Contracts or the Office of Sponsored Programs for specific guidance relating to individual grants.

Below are a few highlighted examples:

### **1. Public Health Service (PHS) Disclosure, including the National Institutes of Health (NIH), and National Science Foundation (NSF) Disclosure**

Federal regulations require that all applicants for funding by grants, contracts or cooperative agreements from the PHS (including but not limited to NIH) as well as other funding agencies and organizations that apply PHS disclosure requirements must disclose to the institution submitting the application any "Significant Financial Interests" as defined in 42 C.F.R. §50.603 that reasonably appear to be related to an Investigator's Institutional Responsibilities (whether or not the Significant Financial Interests are related to the research at hand). It should be emphasized that each Investigator, including the Principal Investigator, co-investigator(s), and all other persons who are responsible for the design, conduct or reporting of the research (including collaborators and consultants) must complete a disclosure form. A new disclosure form must be submitted for every grant application including non-competing or competing continuations, at least annually. A new disclosure also must immediately be submitted upon an Investigator acquiring or discovering a Significant Financial Interest. Furthermore, each Investigator must complete COI training annually.

Significant Financial Interests create Conflicts of Interest that require reporting to the Office of Compliance and Corporate Integrity and the National Institutes of Health ("NIH") if it is a NIH research project. All NIH Financial Conflicts of Interest must be reported. A report to NIH must be filed in the Electronic Research Administration (eRA) Common FCOI reporting tool. The FCOI module can be accessed via eRA Commons. Additionally, individuals must annually disclose his or her FCOI Report to NIH at the same time as when he or she submits the annual progress report, including multi-year program reports or at the time of an extension.

Any individual carrying out research or other activities supported by the the PHS or supported by another sponsor that mandates compliance with the PHS regulations must refer to MSM's Research Conflicts of Interest Policy for the definition of "significant financial interests" and for specific procedures applicable to PHS funding.

All researchers applying for funding from the NSF must comply with applicable NSF requirements regarding COI disclosure.

### **2. Food & Drug Administration (FDA) Disclosure**

Individuals involved in FDA regulated research, such as clinical trials of drugs, biologicals or devices under an Investigational New Drug (IND) Application or an

Investigational Device Exemption (IDE), are required to submit a study-specific disclosure on FDA specified forms. The nature and value of holdings, which must be disclosed, are specified in FDA regulations and in the instructions to the disclosure forms. It is the responsibility of the "Sponsor" to collect these disclosure forms from individual investigators and submit them to the FDA. Individuals should complete these forms with care, since errors could have serious consequences. Holders of the IND or IDE for a study should be especially diligent regarding compliance with FDA regulations since the FDA tends to hold the individual investigator and sponsor responsible for any violations.

### **3. Institutional Review Board (IRB) Disclosure**

MSM's IRB requires a protocol-specific disclosure of any relationships or financial holdings which could give the appearance of a conflict of interest. The disclosure is required of the Principal Investigator, each co-investigator and any other person responsible for the design, conduct or reporting of the research described in the protocol. Information regarding possible conflicts of interest of investigators might influence some potential research subjects as to whether to participate in the research and such information should therefore be provided to potential research subjects in order that they can give appropriately informed consent. The disclosure is research study (protocol) specific, so a new disclosure must be submitted with each new IRB Protocol Application. This applies to new submissions, revisions and continuing reviews.

### **4. Industrial Sponsors of Research Disclosures**

Identifying potential conflicts of interest in regard to agreements with industrial sponsors of research is important in negotiation of and compliance with the terms of agreements with industrial sponsors of research. For example, sponsors may require MSM to confirm that the investigators do not have any potential conflicts of interest related to their participation in the proposed research. A conflict might also arise when a researcher has interests in a parent company that owns a subsidiary that is directly sponsoring the study. In addition, the existence of multiple sources for funding, and commitments made in Material Transfer Agreements, can create situations where there are conflicting obligations to different sponsors as well as to providers of materials. The disclosure required is specific for the studies to be supported by the proposed industrial agreement.

## **XII. Disclosure Requirements**

Upon hire and on an annual basis, all members of the MSM Community must provide information on the nature and extent of their Outside Professional Activities and Financial Interests related to their Institutional responsibilities. This occurs by disclosure in Morehouse School of Medicine's electronic disclosure system, COI-Smart. The information required to be disclosed is specified in the disclosure questionnaire.

If there is doubt about the existence of an actual or apparent Conflict of Commitment or Conflict of Interest, or uncertainty as to the relation of an Outside Professional Activity or Financial Interest to one's Institutional Responsibilities, the individual should err on the side of

disclosing it for review and approval. Each school of MSM may request more, but not less, information than that specified in this Policy and/or in the disclosure questionnaire.

The confidentiality of the disclosures will be respected as far as possible. In particular, the information on the questionnaire will not be shared except with authorized individuals in the conduct of their official University responsibilities, and for members of the MSM community with clinical responsibilities, with appropriate officials responsible for oversight of clinical responsibilities; and where required contractually or by law in connection with sponsored funding, with the research sponsors or through public disclosure.

### **XIII. Disclosure Updates**

All members of the MSM community are expected to update their disclosure information outside of the annual disclosure process if an external activity or Financial Interest arises with the potential to impact one's Institutional Responsibilities in a meaningful or significant way. The disclosure should be updated whenever the information provided changes materially. The updated disclosure should be submitted as soon as possible, but no later than 30 days after the individual's knowledge of such events.

### **XIV. Consequences of Violating this Policy**

Failure to comply with this Policy, including failure to disclose or submission of an incomplete, erroneous, or misleading disclosure; failure to submit other information required by this Policy; or failure to comply with prescribed management plans and/or monitoring procedures, will be handled in accordance with MSM disciplinary policies and procedures and may result in disciplinary action, up to and including termination of employment or faculty appointment.

### **XV. Related Policies or Procedures**

*Research Conflicts of Interests Policy*

*Policy and Guidelines for Interactions with Pharmaceutical, Biotechnology, Medical Device and Hospital and Research Equipment Supply Industry.*